Standards Update
- ISO 13485, 14971, 15223

Paul Sim – Knowledge Solutions
Medical Devices Knowledge Manager

US Roadshows – October 2016
1 - Introduction
2 - ISO 9001:2015
3 - ISO 13485:2016
   - Timings
   - interrelationship with the EU Medical Device Regulations
4 - ISO 14971
5 - ISO 15223
EN ISO 13485:2012
What is the difference?

ISO 13485:2003
- The previous International Standard

EN ISO 13485:2003
- The previous version of the European Harmonised Standard
- Obsolete as of 30 August 2012

EN ISO 13485:2012
- Changes within Foreword & Annex Zs only
- **No change** to requirements (Normative Text)
- Annex Z’s to provide greater clarity on applicability & alignment with AIMDD, MDD & IVDD
### Relationship between Annex II of 93/42/EEC and clauses of ISO 13485

<table>
<thead>
<tr>
<th>Paragraph of Directive 93/42/EEC, Annex II</th>
<th>Clause(s) of EN ISO 13485</th>
<th>Comments/Qualifying remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 first sentence</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 1(^{st}) indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 2(^{nd}) indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 3(^{rd}) indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 4(^{th}) indent</td>
<td>4.1, 4.2</td>
<td>Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.</td>
</tr>
<tr>
<td>3.1 second sentence 5(^{th}) indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 6(^{th}) indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 7(^{th}) indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.2 first paragraph first sentence</td>
<td></td>
<td>Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined,</td>
</tr>
</tbody>
</table>
New ISO Management Systems High Level Structure

- New and revised ISO MS Standards now using ISO Annex SL: A standard for standard writers
- Provides a 10 clause high-level structure and common text
- Standardises terminology for fundamental Management System requirements
- Follows the Plan → Do → Check → Act (PDCA) principle
New
ISO 9001:2015

10 Clause Structure

NOTE: 5 year review due 2020

Published February 26, 2016
ISO 13485:2016 – What’s New?

- Many additions
- Some new requirements
- Some expansion & clarification
- Increased clarity of interrelationship between clauses and requirements
Changes to Clause Numbering

• Due to the inclusion of several new clauses, several sub-clauses have been re-numbered.

• This presentation covers changes to content, not every sub-clause re-number.

• In order to work with Medical Device Single Audit Program (MDSAP) levels of non-conformance grading, the clauses and sub-clauses required formatting

  * See GHTF Document SG3 N19
## Regulatory Requirements

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>“Regulatory requirements”</td>
<td></td>
</tr>
<tr>
<td><strong>Appears 9 times</strong></td>
<td><strong>Appears 37 times</strong></td>
</tr>
</tbody>
</table>

* Within Normative Requirements, i.e. Clauses: 4 - 8
## Objectives and scope

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Objectives</strong></td>
<td>Facilitate harmonization</td>
<td>Facilitate global alignment</td>
</tr>
<tr>
<td><strong>Scope &amp; Role</strong></td>
<td>Organizations provide Medical devices and related services</td>
<td>Organizations can be involved in one or more stages of the life-cycle including the design and development, production, storage and distribution, installation, or servicing of a medical device and the design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product including quality management system-related services to such organizations.</td>
</tr>
</tbody>
</table>
### Definitions

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Active implantable medical device</td>
<td>Advisory notice</td>
<td></td>
</tr>
<tr>
<td>Active medical device</td>
<td>Clinical evaluation</td>
<td></td>
</tr>
<tr>
<td>Advisory notice</td>
<td>Complaint</td>
<td></td>
</tr>
<tr>
<td>Customer complaint</td>
<td>Distributor</td>
<td></td>
</tr>
<tr>
<td>Implantable medical device</td>
<td>Implantable medical device</td>
<td></td>
</tr>
<tr>
<td>Labelling</td>
<td>Importer</td>
<td></td>
</tr>
<tr>
<td>Medical Device</td>
<td>Life cycle</td>
<td></td>
</tr>
<tr>
<td>Sterile medical device</td>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical device</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medical device family</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Performance evaluation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post market surveillance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Purchased product</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Risk management</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterile barrier system</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterile medical device</td>
<td></td>
</tr>
</tbody>
</table>
## 4 - Quality Management System

### 4.1 - 2
#### General Requirements
- + Document role(s) undertaken by organization under regulatory requirements
- + Risk based approach to control QMS processes

### 4.1.3 - 5
#### General requirements
- Records to meet regulatory requirements. Change control
- For outsourced processes control based on risk and ability

### 4.1.6
#### General Requirements
- + Requirement to validate the computer software used for QMS prior to initial use & after changes

### 4.2
#### Documentation Requirements
- Medical Device File
  - + Detailed list of items (a-f) that shall be included to meet regulatory requirements
5 – Management Responsibility

5 General requirements

Increased emphasis on regulatory requirements

5.5.1 Responsibility & Authority

Top mgmt shall DOCUMENT the interrelation of all personnel who....

5.5.2 Management representative

Focus on awareness of quality management system and the removal of customer requirements from bullet c)

5.6 Management review

Procedures required, document planned intervals

+ More bullet points for inputs, new bullet for outputs
6 – Resource Management

6.2 Human resources

Shall document the processes for establishing competence, providing training, and ensuring awareness.

+ Maintain competency
+ NOTE Methodology used to check effectiveness to be proportionate to risk associated with work for which training or other action is provided.

6.3 Infrastructure

+ Prevent product mix up, ensure orderly handling;
  Maintenance of equipment applies to production, control of work env, monitor and measurement.
6.4 – Work environment and contamination control

6.4.1 Work environment

Adds documentation requirements, competence for temporary work, NOTE refers to ISO 14644 and ISO 14698 for further information.

6.4.2 Contamination control

For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.
7 – Product Realization

7.1 Planning of product realization

+ Documented processes for risk management
+ Required planning for verification, validation, monitoring, measurement, inspection, test activities, handling, storage, distribution, & traceability

7.2.1 Determination of product requirements

+ Any user training needed to ensure specified performance and safe use of the medical device

7.2.2 Review of product requirements

+ Applicable regulatory requirements are met
+ Any user training identified in accordance with 7.2.1 is available or planned to be available...

7.2.3 Communication

+ The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3.2</td>
<td>Design &amp; development planning</td>
</tr>
<tr>
<td></td>
<td>+ List of items to document:</td>
</tr>
<tr>
<td></td>
<td>+ Traceability of outputs to inputs</td>
</tr>
<tr>
<td></td>
<td>+ Resources including competence</td>
</tr>
<tr>
<td>7.3.3 - 5</td>
<td>D &amp; D Inputs, outputs, review</td>
</tr>
<tr>
<td></td>
<td>Inputs + Usability, standards, ability to verify/validate</td>
</tr>
<tr>
<td></td>
<td>Review + specific record requirements</td>
</tr>
<tr>
<td>7.3.6 &amp; 7</td>
<td>Design &amp; development V/V</td>
</tr>
<tr>
<td></td>
<td>Requirement to document: the V/V plan, the methods of V/V, criteria for acceptance, rationale for sample sizes. Connections and interfaces</td>
</tr>
<tr>
<td>7.3.6 &amp; 7</td>
<td>Design &amp; development V/V</td>
</tr>
<tr>
<td></td>
<td>V/V of device interfaces. All validation activity must be conducted on representative product or documented equivalent devices</td>
</tr>
</tbody>
</table>
7 – Product Realization (continued)

7.3.8 Design & development transfer

New sub-clause
Procedures required

7.3.9 Design and development changes

Was 7.3.7 – more detail added. Link to risk management and product realization added. Detail regarding determining significance of change added.

7.3.10 Design and development files

New sub-clause
+ Shall maintain a D&D file for each medical device type or family. This file shall include or reference records generated to demonstrate conformity to the requirements for D&D and records for D&D changes.
7 – Product Realization (continued)

7.4.1 Purchasing
Criteria for evaluation and selection of suppliers includes performance and risk. Supplier performance monitoring as part of re-evaluation process, additional record requirements.

7.4.2 Purchasing information
+ Purchasing information to include, as applicable product specifications. Suppliers to agree to prior notification of changes.

7.4.3 Verification of purchased product
+ Extent of verification based on risk/supplier evaluation and link to change control.
7 – Product Realization (continued)

7.5.1 Control of production & service provision
Production and service provisions must be monitored and controlled as well as planned and carried out to ensure product conforms to specifications.

7.5.2 Cleanliness & contamination control
Similar to 2003 requirements, adds contamination control.

7.5.3 Installation activities
Similar to 2003 requirements.

7.5.4 Servicing activities
Servicing activity records must be analyzed to determine if the issue is a complaint or must be utilized as an improvement input.
7 – Product Realization (continued)

7.5.6 Validation of processes for production and service provision

+ Validate processes where output cannot be or IS NOT verified, + need for procedures, + Use appropriate statistical techniques, rationale for sample sizes, approval of changes, and validation of software after any changes, risk based

7.5.8 Identification

+ UDI where required by national or regional regulations
+ Requirement for procedures for separation of returned products from conforming product

7.5.7 Validation of sterilization and sterile barriers

+ Added sterile barriers
+ Validation required prior to implementation, changes
+ Document results, conclusions, actions
7 – Product Realization (continued)

7.5.9 Traceability
Similar to 2003 version

7.5.10 Customer property
Consistent with 7.5.4 of current document

7.5.11 Preservation of product
Specific reference to packaging and shipping containers, other measures
+ Distribution is specified

7.6 Control of monitoring and measuring equipment
Requirements for the validation of the application of computer software used for monitoring and measurement of requirements added to this clause. Risk based approach required.
8 – Measurement, Analysis and Improvement

8.2 Monitoring and measurement

+ Feedback procedures, input to risk management and improvement process. Clause strengthened.

8.2.2 and 8.2.3 Complaint handling & Reporting to regulatory authorities

New Clauses

Requires procedures for timely complaint handling, investigation, regulatory notification and more

Procedures for reporting to regulatory authorities regarding complaints are required
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
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<tbody>
<tr>
<td>8.2.6</td>
<td>Monitoring and measurement of product</td>
</tr>
<tr>
<td></td>
<td>+ Test equipment shall be identified as appropriate</td>
</tr>
<tr>
<td>8.3</td>
<td>Control of non conforming product</td>
</tr>
<tr>
<td></td>
<td>+ details in respect of controls, concessions, records. Clause restructured</td>
</tr>
<tr>
<td>8.5.2 &amp; 8.5.3</td>
<td>Corrective &amp; Preventive action</td>
</tr>
<tr>
<td></td>
<td>Verifying that CAPA does not have an adverse effect, actions to be taken without undue delay</td>
</tr>
</tbody>
</table>
Areas of Increased Emphasis

- Regulatory Requirements
- Risk Management
- Validation, Verification & Design Transfer
- Outsourced Processes & Supplier Control
- Feedback

ISO 13485 3rd Edition

Improved linkage of clauses
ISO 13485:2016 Annexes

Annex A
• Comparison of content between ISO 13485:2003 and ISO 13485:2016

Annex B
• Correspondence between ISO 13485:2016 and ISO 9001:2015

European Annexes ZA (AI MD), ZB (MDD) and ZC (IVD)
• Identifies relationship between the European Standard (EN ISO 13485:2016?) and Conformity Assessment Requirements of the respective EU Medical Device Directives via each conformity assessment route for each directive
ISO 13485:2016 Annexes

European Annexes ZA (AI MD), ZB (MDD) and ZC (IVD)

- Identifies relationship between the European Standard (EN ISO 13485:2016) and Conformity Assessment Requirements of the respective EU Medical Device Directives via each conformity assessment route for each directive

**Table ZB.1 — Correspondence between this International Standard and Annex II of Directive 93/42/EEC (as amended)**

<table>
<thead>
<tr>
<th>Paragraph of Directive 93/42/EEC, Annex II</th>
<th>Clause(s) of this International Standard</th>
<th>Comments/Qualifying remarks</th>
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</thead>
<tbody>
<tr>
<td>3.1, 1st sentence</td>
<td></td>
<td>Not covered.</td>
</tr>
<tr>
<td>3.1, 2nd sentence, 1st indent</td>
<td></td>
<td>Not covered.</td>
</tr>
<tr>
<td>3.1, 2nd sentence, 2nd indent</td>
<td></td>
<td>Not covered.</td>
</tr>
<tr>
<td>3.1, 2nd sentence, 3rd indent</td>
<td></td>
<td>Not covered.</td>
</tr>
<tr>
<td>3.1, 2nd sentence, 4th indent</td>
<td>4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5</td>
<td>Covered. The documentation required in this International Standard covers the quality system documentation meant in 3.2 of Annex II when the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.</td>
</tr>
</tbody>
</table>

**NOTE:** European Annexes will require revision following publication of the EU Medical Devices Regulation
Timings
ISO 13485:2016 – Timings

25 February 2016
ISO 13485:2016 published
BS EN ISO 13485:2016 published
3 year transition period now started

March – December 2016
European Harmonization

28 February 2018
Cease issue of ISO 13485:2003 Certificates
NOTE: Draft guidance - No new ISO 13485:2003 certificates issued in final year of transition

28 February 2019
End of 3 year transition

28 February 2018
Cease issue of ISO 13485:2003 Certificates
NOTE: Draft guidance - No new ISO 13485:2003 certificates issued in final year of transition

28 February 2019
End of 3 year transition
Interrelationship with the EU Medical Device Regulations
Article 8 - General obligations of the manufacturer

• … manufacturers of devices … shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this regulation in the most effective manner.

• The quality management system consists of
  • … manufacturer’s organization dealing with the quality of processes, procedures and devices
  • … structure, responsibilities, procedures, processes and management resources to … to achieve compliance with the provisions of this regulation.
The quality management system shall address at least:

- a strategy for regulatory compliance including management change of modifications to the devices covered by the system
- identification of applicable general safety and performance requirements and exploration of options to address these
- the responsibility of the management
- resource management, including selection and control of suppliers and sub-contractors;
- risk management
- clinical evaluation, including post-market clinical follow-up
- product realisation, including planning, design, development, production and service provision;
- control of the UDI-Code
- setting-up, implementation and maintenance of a systematic post-market surveillance plan
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders
- processes for reporting of serious incidents and field safety corrective actions in the context of vigilance
- management of corrective and preventive actions and verification of their effectiveness
- processes for monitoring and measurement of output, data analysis and product improvement
Annex VIII - Conformity assessment based on Quality Management System Assurance and assessment of Technical Documentation

- ...the documentation … shall include
  - the manufacturer’s quality objectives;
  - the organisation of the business and in particular:
    - the organisational structures …, the responsibilities ..and …authority
    - the methods of monitoring the efficient operation of the quality management system …
  - where the design, manufacture and/or final verification and testing … is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied …
  - .. mandate for the designation of an authorised representative;
Procedures and techniques for monitoring, verifying, validating and controlling the design

• strategy for regulatory compliance,
  • processes for identification of relevant legal requirements
  • qualification [device or personnel?] 
  • classification 
  • handling of equivalence 
  • choice of and compliance with conformity assessment procedures

• identification of applicable general safety and performance requirements and solutions
  • consideration of applicable Common Specifications (CS) and harmonized standards or equivalent solutions

• solutions to address the applicable specific requirements regarding design and construction, including appropriate preclinical evaluation

• specific requirements regarding the information to be supplied with the device

• device identification procedures drawn up and kept up to date from drawings specifications or other relevant documents at every stage of manufacture

• management of design or quality management system changes
Proposal for a cross reference table, if accepted might be published as a CEN Technical Report

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>5.</td>
<td>Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation.</td>
<td>Annex VIII 3.2 paragraph 2 c) indent 8</td>
<td>management of design or quality management system changes;</td>
<td>4.1, 4.2.4.7.8</td>
<td>EN ISO 13485:2016 requires the quality management system to comply with applicable regulatory requirements but does not explicitly refer to the European regulations.</td>
</tr>
<tr>
<td></td>
<td>Changes in product design or characteristics and changes in the harmonized standards or CS by reference to which conformity of a product is declared shall be adequately taken into account in a timely manner.</td>
<td></td>
<td></td>
<td></td>
<td>EN ISO 13485 includes general reference to regulatory requirements and standards as design and development inputs (7.3.3). Identification of new or revised regulatory requirements is identified as an input into Management Review (5.6.3) and changes needed as a result of such changes required as outputs of Management Review (5.6.3). Common specifications are not explicitly mentioned.</td>
</tr>
<tr>
<td></td>
<td>Proportionate to the risk class and the type of device, manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain.</td>
<td>Annex VIII 1.</td>
<td>The manufacturer shall establish, document and implement a quality management system as described in Section 3.3 and is subject to audit as laid down in Sections 3.3 and 3.4, and to the surveillance as specified in Section 4.</td>
<td>4.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Implementation of the quality management system shall ensure the compliance with the provisions of this Regulation. All the elements, requirements and provisions adopted by the manufacturer for his quality management system as specified in Section 3.3 and is subject to audit as laid down in Sections 3.3 and 3.4, and to the surveillance as specified in Section 4.</td>
<td>Annex VIII 3.2</td>
<td></td>
<td>1.4.1, 4.2.5.6.8</td>
<td>EN ISO 13485 requires that the effectiveness of the quality management system is maintained and provides requirements for improvement processes, but not that...</td>
</tr>
</tbody>
</table>
MDR + ISO 13485 status - timelines

Development of implementing legislation

2016
2017
2019
2020
2022
2024

Transition period of three years

the detailed MDR status/timelines will be presented by my colleague Ibim Tariah

MDR

ISO 13485:2016

Transition Period ends February 2019

[Current European Version EN ISO 14971:2012]
ISO 14971:

Risk Management

- **Current status**
  - This standard is dual logo with IEC, and for IEC managed by Sub Committee 62A, and for ISOTC 210 managed by JWG 1, under ISO lead with alternating ISO & IEC Convenors
  - Systematic review started 15th October 2015, closed 15th March 2016, P members voting too confirm
  - JWG1 meeting in Tampa, Florida in June 2016, reviewed the comments and other business relating to Guide 63 and Health IT Software.
  - Comprehensive debate, including need for further guidance, and particular areas needing follow up, including review/update ISO TS 24971, with a suggestion that comprehensive guidance might address some of the issues raised during the meeting.
  - As a result and following consultations with ISOTC Chairman, Chairman IEC/SC 62A and the respective secretariats – the decision was made to defer a final decision to the ISOTC 210 Plenary meeting in November 2016 which is after the next IEC/SC 62A meeting in October 2016.
  - US TAG commentary
  - Sorry best I can offer
ISO 15223 - Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied –

Brief update
ISO 15223

Symbols

• ISO 15223 - Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part I General requirements
  • FDIS positive vote - 21st September 2016, Publication November?
  • EN Version & Harmonisation?

• Part II Symbol Development, selection and validation
  • 5 year systematic review closed 25th August 2016, result CONFIRM
  • One comment – process for new symbols, too complex

• ISO 7000 & ISO TC 145

• EU Medical Device Regulation - considerations for symbols proposal & development, UK proposals to be submitted to ISO TC210 WG3
NOTE: initial list of UK proposed symbols for incorporating into the next edition of ISO 15223-1:201X
All Clause references (red boxes) are from Annex 1 - General safety & performance requirements

19.2 (q)
Symbol 1: Medical Device

19.2 (e)
Symbol 10: Tissues and Cells of Human origin

19.2a (j)
Symbol 12: Tissues and cells of Animal Origin

19.2 (h)
Symbol 14: Sterile instructions
MD

MDR Annex 1 19.2 q

SRN

XXXXXX

GMDN

XXXXX

UDI

US FDA 21 CFR 801.40 c – Disclosure of AI DC technology & MDR Annex I 19.2 h

Warning: These are concept designs do not use
Nanomaterial

Single Patient Use

Distributor

Tissues & Cells of Human Origin

Contains blood products

Hb!

Article 18 CE marking of Conformity
4) “CE mark may be followed by a pictogram or other mark indicating a special risk of use”

Warning: These are concept designs do not use

Annex I, 19.2a – on sterile packaging
(j) an instruction to check the Instructions For Use for what to do if the sterile packaging is damaged etc

Sterile Instructions

Cannot use a “bull” outline

Tissue & Cells of Animal Origin
Sample template of the data and information required for each proposed symbol:

Symbol 1: Insert name

Description of symbol
This symbol indicates...

Statement of need
The benefit of introducing this symbol is... (e.g., avoid multiple languages)
Regulatory – only EU or further afield? (see 4.1.2 of 15223-x)
The target audience of this symbol is... (e.g., profession users, lay users), with [insert level of training/knowledge] and [experience with medical device].
The symbol has a horizontal application to a wide range of medical devices/restricted range of device types.

Risk assessment
The risk associated with this symbol is [insert risk level]. This is because...
Identification of any particular considerations such as orientation which can affect legibility, reproduction, or understanding.

Existing/related symbols
Are there already any symbols with a similar meaning standardized? Or symbols we have based the proposed design on?

Design concepts for symbol

Feedback we have received on initial analysis of symbols
Contact details

Bill Enos (US Based)
Global Head – Microbiology
Bill.enos@bsigroup.com

Paul Sim (UK Based)
Medical Devices Knowledge Manager
Paul.sim@bsigroup.com
Thank you for your time and attention

Questions?